

Applicant: Reiko M. Nakamura
Serial No.: 09/877,802
Supplemental Preliminary Amendment

In the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

Claims 1-20 Previously Canceled

Claim 21-33 Previously Canceled

Claim 34. (Currently Amended) A transdermal device comprising:

an antigen composition applied to or impregnated on a transdermal delivery vehicle comprising an antigen derived from MPB64 or MPT64 ~~or an antigen with the characteristics of MPB64 or MPT64 and fragments thereof wherein the transdermal device can distinguish between an active mycobacterium species infection and a *Mycobacterium tuberculosis* infection controlled by the patient's natural immune mechanisms or controlled by drug therapy.~~

Claim 35. (Previously Presented) The transdermal device of Claim 34, wherein the antigen composition further comprises a surfactant.

Claim 36. (Previously Presented) The transdermal device of Claim 35, wherein the surfactant is a non-ionic surfactant.

Claim 37. (Previously Presented) The transdermal device of Claim 36, wherein the surfactant is a polyoxyethylene sorbitan derivative.

Claim 38. (Previously Presented) The transdermal device of Claim 37, wherein the polyoxyethylene sorbitan derivative is polyoxyethylene sorbitan monooleate.

Claim 39. (Previously Presented) The transdermal device of claim 34, wherein the transdermal device is medical tape, medical plaster, gauze, patch, adhesive solution, or a patch band.

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Claim 40. (Currently Amended) A method of distinguishing a patient with an active tuberculosis infection from a patient that has been exposed to a *Mycobacterium tuberculosis* but has controlled the infection by natural immune mechanisms comprising:

exposing the patient to a transdermal delivery device with an antigen composition applied to or impregnated on the transdermal delivery device wherein the antigen composition is an antigen derived from MPB64 or MPT64 ~~or an antigen with the characteristics of MPB64 or MPT64 and fragments thereof wherein the transdermal device can distinguish between an active mycobacterium species infection and a *Mycobacterium tuberculosis* infection controlled by the patient's natural immune mechanisms or controlled by drug therapy.~~

Claim 41. (Previously Presented) The method of Claim 40, wherein the antigen composition further comprises a surfactant.

Claim 42. (Previously Presented) The method of Claim 41, wherein the surfactant is a non-ionic surfactant.

Claim 43. (Previously Presented) The method of Claim 42, wherein the surfactant is a polyoxyethylene sorbitan derivative.

Claim 44. (Previously Presented) The method of Claim 43, wherein the polyoxyethylene sorbitan derivative is polyoxyethylene sorbitan monooleate.

Claim 45. (Previously Presented) The method of Claim 40, wherein the transdermal device is medical tape, medical plaster, gauze, patch, adhesive solution, or a patch band.

Claim 46. (Currently Amended) A method of diagnosing infection with *Mycobacterium tuberculosis* in a patient with immune deficiency disease (AIDS):
exposing the patient to a transdermal delivery device with an antigen composition applied to or impregnated on the transdermal delivery device wherein the antigen composition is an antigen

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derived from MPB64 or MPT64 ~~or an antigen with the characteristics of MPB64 or MPT64 and~~ fragments thereof.

Claim 47. (Previously Presented) The method of Claim 46, wherein the antigen composition further comprises a surfactant.

Claim 48. (Previously Presented) The method of Claim 47, wherein the surfactant is a non-ionic surfactant.

Claim 49. (Previously Presented) The method of Claim 48, wherein the surfactant is a polyoxyethylene sorbitan derivative.

Claim 50. (Previously Presented) The method of Claim 49, wherein the polyoxyethylene sorbitan derivative is polyoxyethylene sorbitan monooleate.

Claim 51. (Previously Presented) The method of claim 46, wherein the transdermal device is medical tape, medical plaster, gauze, patch, adhesive solution, or a patch band.

Claim 52. (Currently Amended) A method of monitoring effect of drug therapy in a patient infected with *Mycobacterium tuberculosis* comprising:

exposing the patient to a transdermal delivery device with an antigen composition applied to or impregnated on the transdermal delivery device wherein the antigen composition is an antigen derived from MPB64 or MPT64 ~~or an antigen with the characteristics of MPB64 or MPT64 and fragments thereof wherein the transdermal device can distinguish between an active mycobacterium species infection and a *Mycobacterium tuberculosis* infection controlled by the patient's natural immune mechanisms or controlled by drug therapy.~~

Claim 53. (New) The method of Claim 52, wherein the antigen composition further comprises a surfactant.

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Claim 54. (New) The method of Claim 53, wherein the surfactant is a non-ionic surfactant.

Claim 55. (New) The method of Claim 54, wherein the surfactant is a polyoxyethylene sorbitan derivative.

Claim 56. (New) The method of Claim 55, wherein the polyoxyethylene sorbitan derivative is polyoxyethylene sorbitan monooleate.

Claim 57. (New) The method of claim 52, wherein the transdermal device is medical tape, medical plaster, gauze, patch, adhesive solution, or a patch band.